

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Robert Galen et al.
Serial No. : Unassigned Art Unit: Unknown
Filed : Herewith Examiner: Unknown
For : Apparatus for Combined Assay for Current Glucose Level and Intermediate or Long-Term Glycemic Control

EXPRESS MAIL LABEL NO.: EL 373 764 339 US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in

§1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with the first or second After Final Submission, therefore:

- Statement in Accordance with §1.97(e) (attached); or
- Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- Statement in Accordance with §1.97(e) (attached); or
- Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

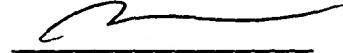
Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

- In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No. 09/477,900), copies are not enclosed herewith.
- If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
- Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).
- There are no listed references which are not in the English language.
- The relevance of those listed references which are not in the English language is as follows:
 - Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.
 - Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/DDI-0028-CON1/MM.

Respectfully submitted,


Mayumi Maeda
Reg. No. 40,075
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(408) 956-4790

DATED: 9/19/03

FORM PTO-1449 US Department of Commerce Patent and Trademark Office		ATTY DOCKET NO.:	SERIAL NO.:
		DDI-0028-CON1	Unassigned
		APPLICANT: Galen et al.	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		FILING DATE: Herewith	GROUP ART UNIT: Not assigned

U. S. PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	3552929	1/5/71	Fields et al.	23	253	
	3802842	4/9/74	Lange et al.	23	253	
	3809605	5/7/74	Schmitt et al.	162	158	
	3897214	7/29/75	Lange et al.	23	253	
	3973849	8/10/76	Jackson et al.	356	97	
	4050898	9/27/77	Goffe, deceased et al.	23	253	
	4042335	8/16/77	Clement	23	253	
	4223995	9/23/80	Fletcher	356	418	
	4269605	5/26/81	Dean et al.			
	4397956	8/9/83	Maggio	436	34	
	4478744	10/23/84	Mezei et al.			
	4482251	11/13/84	Saylor	356	418	
	4545382	10/8/85	Higgins et al.	128	635	
	4642295	2/10/87	Baker	436	87	
	4645742	2/24/87	Baker	436	15	
	4681444	7/21/87	Ferber et al.	356	319	
	4729657	3/8/88	Cooper et al.	356	319	
	4744657	5/17/88	Aralis et al.	356	319	
	4806468	2/21/89	Wagner et al.	435	7	
	4852025	7/25/89	Herpchbohm	364	551.01	

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 US Department of Commerce Patent and Trademark Office	ATTY DOCKET NO.:	SERIAL NO.:
	DDI-0028-CON1	Unassigned
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	APPLICANT: Galen et al.	
	FILING DATE: Herewith	GROUP ART UNIT: Not assigned

	4866644	9/12/89	Schenk et al.	364	571.02	
	4935346	6/19/90	Phillips et al.	435	14	
	4956301	9/11/90	Ismail et al.	436	87	
	4999582	3/12/91	Parks et al.			
	5002893	3/26/91	Rosenthal	436	87	
	5049487	9/17/91	Phillips et al.	435	4	
	5059394	10/22/91	Phillips et al.	422	68.1	
	5075077	12/24/91	Durley III et al.	436	170X	
	5110745	5/5/92	Kricka et al.			
	5169787	12/8/92	Knappe et al.	436	169	
	5179005	1/12/93	Phillips et al.	435	14	
	5183739	2/2/93	Cohen	435	7.23	
	5206144	4/27/93	Zeuthen et al.	435	7.25	
	5215716	6/1/93	Arai			
	5223219	6/29/93	Subramanian et al.	422	55	
	5243516	9/7/93	White			
	5258163	11/2/93	Krause et al.	422	58	
	5271895	12/21/93	McCroskey et al.	422	58	
	5281395	1/25/94	Markart et al.	422	82.05	
	5284777	2/8/94	Rosenthal et al.	436	518	
	5304468	4/19/94	Phillips et al.			
	5366868	11/22/94	Sakamoto			

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 US Department of Commerce Patent and Trademark Office		ATTY DOCKET NO.:	SERIAL NO.:
		DDI-0028-CON1	Unassigned
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT: Galen et al.	
		FILING DATE: Herewith	GROUP ART UNIT: Not assigned

		5384239	1/24/95	Saunders				
		5470752	11/28/95	Burd et al.				

FOREIGN PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	NAME	CLASS	SUB- CLASS	TRANSLATION (YES/NO)
	0473189A2	3/4/92	European	Sakamoto			
	0388782	9/26/90	European	Chen			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

	Armbruster, "Diabetes mellitus, protein glycation, and laboratory assays for monitoring long-term glycemic control." <u>Clinical Laboratory Science</u> , 3(3):184-188 (1990).
	Armbruster, "Fructosamine: Structure, Analysis, and Clinical Usefulness." <u>Clinical Chemistry</u> , 33(12):2153-2163 (1987).
	Baker et al., "Clinical usefulness of estimation of serum fructosamine concentration as a screening test for diabetes mellitus." <u>British Med. J.</u> , 287:863-867 (1983).
	Benjamin and Sacks, "Glycated protein update: implications of recent studies, including the diabetes control and complications trial." <u>Clin. Chem.</u> , 40(5):683-687 (1994).
	Caines et al., "Colorimetric determination of non-enzymatically glycated albumin." <u>Clinical Biochemistry</u> , 19:26-30 (February 1986).

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 US Department of Commerce Patent and Trademark Office		ATTY DOCKET NO.:	SERIAL NO.:
		DDI-0028-CON1	Unassigned
		APPLICANT: Galen et al.	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		FILING DATE: Herewith	GROUP ART UNIT: Not assigned

		Candiloro, "Decreased Erythrocyte Membrane Fluidity in Poorly Controlled IDDM." <u>Diabetes Care</u> , 18(4) 549-551 (1995)
		Cefalu et al., "Serum fructosamine as a screening test for diabetes in the elderly: a pilot study." <u>JAGS</u> , 41:1090-1094 (1993).
		Dix et al., "Glycohemoglobin and glucose tolerance tests compared as indicators of borderline diabetes." <u>Clin. Chem.</u> , 25(6):877-879 (1979).
		Dods and Bolmey, "Glycosylated hemoglobin assay and oral glucose tolerance test compared for detection of diabetes mellitus." <u>Clin. Chem.</u> , 25(5):764-768 (1979).
		Goldstein et al., "Is glycohemoglobin testing useful in diabetes mellitus? Lessons from the diabetes control and complications trial." <u>Clin. Chem.</u> , 40(8):1637-1640 (1994).
		Goldstein and Little, "The impact of the diabetes control and complications trial on the clinical laboratory." <u>Viewpoints</u> , 4 (1993).
		Guillausseau et al., "Comparison of HbA ₁ and fructosamine in diagnosis of glucose-tolerance abnormalities." <u>Diabetes Care</u> 13(8):898-890 (1990).
		Johnson et al., "Fructosamine: a new approach to the estimation of serum glycosylprotein. An index of diabetic control." <u>Clinica Chimica Acta</u> , 127:87-95 (1982).
		Kahn, "Tight blood glucose control shown beneficial for diabetes." <u>Clin. Chem. News</u> , 19(9) (1993).
		Larsen et al., "Effect of long-term monitoring of glycosylated hemoglobin levels in insulin-dependent diabetes mellitus." <u>New England J. of Med.</u> , 323(15):1021-1025 (1990).
		Pamphlet Insert to the Abbott Vision System, (1993)
		Pamphlet Insert to the Lifescan, ONE TOUCH II Blood Glucose Meter, (1990)

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT BY APPLICANT	US Department of Commerce Patent and Trademark Office	ATTY DOCKET NO.:	SERIAL NO.:
	DDI-0028-CON1	Unassigned	
	APPLICANT: Galen et al.		
	FILING DATE: Herewith	GROUP ART UNIT: Not assigned	

	Rosen, "Protein-Bound glucose as a screening test for diabetes." <u>Hospital Practice</u> , 27:59-61 (1992).
	Rowe DJF, "The Measurement and Clinical Significance of Glycated Proteins." <u>Practical Diabetes</u> , 6(6) 256-260 (1989)
	Shima et al., "The relative value of glycated albumin, hemoglobin A _{1c} and fructosamine when screening for diabetes mellitus." <u>Diabetes Research and Clin. Practice</u> , 7:243-250 (1989).
	Searcy and Bolland, "Fructosamine: The next step in diabetic management." <u>Amer. Clin. Lab.</u> 12(8) 1993.
	Thbsalemans et al., "The value of HbA ₁ and fructosamine in predicting impaired glucose tolerance - an alternative to OGTT to detect diabetes mellitus or gestational diabetes." <u>Ann. Clin. Biochem.</u> , 24:447-452 (1987).

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.